

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 IN RE: NEW ENGLAND : MDL No. 2419

5 COMPOUNDING PHARMACY, INC. : Docket No.:

6 PRODUCTS LIABILITY LITIGATION: 1:13-md-2419(RWZ)

7 -----:

8 This document relates to: :

9 :

10 ARNETTA, ET AL v. BOX HILL :

11 SURGERY CENTER, LLC, ET AL :

12 No. 1:14-cv-14022-RWZ :

13 :

14 BOWMAN, ET AL v. BOX HILL :

15 SURGERY CENTER, LLC, ET AL :

16 No. 1:14-cv-14028-RWZ :

17 :

18 DAVIS, ET AL v. BOX HILL :

19 SURGERY CENTER, LLC, ET AL :

20 No. 1:14-cv-14033-RWZ :

21 :

<p style="text-align: right;">Page 2</p> <p>1 DREISCH, ET AL v. BOX HILL : 2 SURGERY CENTER, LLC, ET AL : 3 No. 1:14-cv-14029-RWZ : 4 : 5 FARTHING, ET AL v. BOX HILL : 6 SURGERY CENTER, LLC, ET AL : 7 No. 1:14-cv-14036-RWZ : 8 : 9 KASHI, ET AL v. BOX HILL : 10 SURGERY CENTER, LLC, ET AL : 11 No. 1:14-cv-14026-RWZ : 12 : 13 TORBECK, ET AL v. BOX HILL : 14 SURGERY CENTER, LLC, ET AL : 15 No. 1:14-cv-14023-RWZ : 16 : 17 HANDY, ET AL v. BOX HILL : 18 SURGERY CENTER, LLC, ET AL : 19 No. 1:14-cv-14019-RWZ : 20 ----- 21</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES: 2 ON BEHALF OF PLAINTIFFS ARNETTA, BOWMAN, 3 DAVIS, DREISCH, FARTHING, KASHI, TORBECK 4 AND HANDY: 5 Law Offices of Peter G. Angelos, P.C. 6 GLENN E. MINTZER, ESQUIRE. 7 gmintzer@lawpga.com. 8 SHARON L. HOUSTON, ESQUIRE. 9 100 North Charles Street. 10 Baltimore, Maryland 21201. 11 (410) 649-2000 12 13 ON BEHALF OF PLAINTIFF ROZEK: 14 Cohen, Placitella & Roth, P.C. 15 HARRY M. ROTH, ESQUIRE. 16 hroth@cprlaw.com. 17 SILVIO A. TRENTALANGE, ESQUIRE. 18 strentalange@cprlaw.com. 19 2001 Market Street, Suite 2900. 20 Philadelphia, Pennsylvania 19103. 21 (215) 567-3500</p>
<p style="text-align: right;">Page 3</p> <p>1 Deposition of STEVEN PAUL COHEN, M.D., 2 was taken via Veritext Virtual on Wednesday, March 3 1, 2017, commencing at 10:10 a.m., at Pessin Katz 4 Law, P.A., 10500 Little Patuxent Parkway, Suite 5 650, Columbia, Maryland, before MICHELE D. LAMBIE, 6 Notary Public. 7 ----- 8 9 10 11 12 ALSO PRESENT; Ashley E. Geno, Esquire 13 (via telephone) 14 Reported By: 15 Michele D. Lambie, CSR-RPR 16 17 18 19 20 21</p>	<p style="text-align: right;">Page 5</p> <p>1 APPEARANCES CONTINUED: 2 ON BEHALF OF THE DEFENDANTS: 3 Pessin Katz Law, P.A. 4 GREGORY K. KIRBY, ESQUIRE. 5 gkirby@plaw.com. 6 901 Dulaney Valley Road. 7 Suite 400. 8 Towson, Maryland 21204. 9 (410) 938-8800 10 11 12 13 14 15 16 17 18 19 20 21</p>

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<p>1 PROCEEDINGS</p> <p>2 (Whereupon, Cohen Deposition Exhibit</p> <p>3 Number 3, Expert Report of Steven Cohen, M.D.,</p> <p>4 premarked for identification.)</p> <p>5 (Whereupon, Cohen Deposition Exhibit</p> <p>6 Number 15, Packing Slips, premarked for</p> <p>7 identification.)</p> <p>8 STEVEN PAUL COHEN, M.D.,</p> <p>9 the Deponent, called for examination by the</p> <p>10 Plaintiffs, being first duly sworn to tell the</p> <p>11 truth, the whole truth, and nothing but the truth,</p> <p>12 testified as follows:</p> <p>13 EXAMINATION</p> <p>14 BY MR. ROTH:</p> <p>15 Q. Dr. Cohen, my name is Harry Roth. I</p> <p>16 represent one of the Plaintiffs here, the Estate of</p> <p>17 Brenda Rozek, and I'm going to be asking you some</p> <p>18 questions as you know. How are you doing?</p> <p>19 A. I'm doing okay. Thanks for asking.</p> <p>20 Q. Thank you for accommodating, and</p> <p>21 Mr. Kirby, thank you as well, for accommodating my</p>	<p>1 records. I can tell you some of the names. I</p> <p>2 can't remember each individual record.</p> <p>3 Q. Do you remember reviewing Brenda Rozek's</p> <p>4 records?</p> <p>5 MR. KIRBY: And I'll just object for the</p> <p>6 record. To the extent that he's a common-issue</p> <p>7 expert, I don't know where the questioning is</p> <p>8 going, but that's -- I'll just object to that.</p> <p>9 He's not a case-specific expert at this point</p> <p>10 necessarily.</p> <p>11 MR. ROTH: Understood.</p> <p>12 THE WITNESS: I believe I reviewed her</p> <p>13 records several months ago. In the past two days,</p> <p>14 I've reviewed about five or six other records, and</p> <p>15 hers was not one of those.</p> <p>16 BY MR. ROTH:</p> <p>17 Q. Did you see in any of the records that</p> <p>18 you reviewed, either months ago or in the last</p> <p>19 couple of days, any indication in Dr. Bhambhani's</p> <p>20 notes as to a particular medical need of one of her</p> <p>21 patients that would require a compounded steroid be</p>

<p style="text-align: right;">Page 150</p> <p>1 milligrams per cc, you would, that would be 4 cc's.</p> <p>2 If you're using 80, that would be 2 cc's to get 160</p> <p>3 milligrams.</p> <p>4 Q. But in any event, 5 milliliters is</p> <p>5 typically not a single dose --</p> <p>6 A. That is correct.</p> <p>7 Q. -- right? And the prescription form also</p> <p>8 says five vials of 5 milliliters per one patient.</p> <p>9 That is certainly not for a single use, correct?</p> <p>10 A. Correct.</p> <p>11 Q. All right. What would Dr. Bhambhani do</p> <p>12 after using one 5 milliliter bottle with the rest</p> <p>13 of the epidural not used in a single patient?</p> <p>14 A. So I think it depended on the scenario.</p> <p>15 If there were, was going to be a break between</p> <p>16 cases and she thought that sterility was</p> <p>17 compromised, she would throw it out. If there was</p> <p>18 another patient that were being done immediately</p> <p>19 afterwards, she would sometimes reuse medication</p> <p>20 from the same vial.</p> <p>21 Q. Are there standards or policies that</p>	<p style="text-align: right;">Page 152</p> <p>1 former president of the North American Spine</p> <p>2 Society and I believe a chair at one of the Spine</p> <p>3 Intervention Society meetings, who says it's very</p> <p>4 reasonable to use, to reuse vials.</p> <p>5 And I can tell you, right or wrong, and I</p> <p>6 don't know the answer to this, that there are many,</p> <p>7 many, many doctors who reuse this when, you know, I</p> <p>8 go around to other, you know, pain treatment</p> <p>9 centers.</p> <p>10 Is it right? I don't know the answer to</p> <p>11 the question, but you, you have to acknowledge that</p> <p>12 if hundreds of doctors do this, if that's your</p> <p>13 definition of standard of care and these people</p> <p>14 think this out, then that might fall within</p> <p>15 standard of care.</p> <p>16 Q. Is there a difference between a multi-use</p> <p>17 and single-use vial?</p> <p>18 MR. KIRBY: Objection to form.</p> <p>19 THE WITNESS: Yeah. A single-use vial</p> <p>20 should be used on one patient; whereas, a multi-use</p> <p>21 vial can be used on more than one patient.</p>
<p style="text-align: right;">Page 151</p> <p>1 apply to using a single vial for multiple patients</p> <p>2 of preservative-free steroids?</p> <p>3 A. So the general rule now is that you</p> <p>4 shouldn't use single-dose vials on multiple</p> <p>5 patients.</p> <p>6 Dr. Bhambhani thought, was under the</p> <p>7 impression that these were multi-dose vials, and</p> <p>8 there are some circumstances in which single-dose</p> <p>9 vials can be reused.</p> <p>10 In fact, I saw a lecture by a guy who is</p> <p>11 on the USP compounding pharmacy committee, and he</p> <p>12 says, you know, under certain circumstances,</p> <p>13 single-use vials can be used on multiple patients</p> <p>14 provided people comply with USP 797.</p> <p>15 During times of shortages, we at Johns</p> <p>16 Hopkins have reused single-use vials, and people</p> <p>17 from pharmacy came down and they said, you know,</p> <p>18 here are the, the ways that you need to do this</p> <p>19 safely, and we complied.</p> <p>20 There are articles in the peer-reviewed</p> <p>21 literature, including one by Ray Baker who is the</p>	<p style="text-align: right;">Page 153</p> <p>1 BY MR. ROTH:</p> <p>2 Q. Does the multi-use vial have some means</p> <p>3 of assuring, if you know, the sterility of the, of</p> <p>4 the steroid?</p> <p>5 A. It usually has some sort of bacterio or</p> <p>6 fungicidal, you know, agent in it, such as benzyl</p> <p>7 alcohol and I think maybe even MGPC at very high</p> <p>8 concentrations.</p> <p>9 Q. In your description of the use of, at</p> <p>10 Hopkins when there was a shortage, what the</p> <p>11 pharmacist told you to do and how to make sure that</p> <p>12 things were sterile, were you actively involved in</p> <p>13 that? Were you one of the doctors who was reusing</p> <p>14 a vial during that shortage period?</p> <p>15 A. So they, they came up and they said,</p> <p>16 There's a shortage, but rather than withhold a</p> <p>17 beneficial treatment from our patients, we decide</p> <p>18 that the, that, you know, the benefits of doing it</p> <p>19 this way outweigh the risks. And, of course, there</p> <p>20 are significant risks to, you know, delaying, you</p> <p>21 know, treatment, and so this is how it can be done</p>